

REMARKS / ARGUMENTS

COMPLIANCE WITH 37 C.F.R. §§ 1.821 – 1.825

The Office Action mailed February 26, 2007, has been received and reviewed. The Office Action alleges the Application fails to comply with the sequence listing rules under 37 C.F.R. §§ 1.821 – 1.825, because peptide sequences appearing in the originally-filed Specification were not identified by a sequence identifier in accordance with 37 C.F.R. § 1.821(d). The Office Action further states: “Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate submission of a substitute specification.”

In order to bring the Application in compliance with the sequence listing rules under 37 C.F.R. §§ 1.821 – 1.825, Applicants submit herewith a Substitute Specification, in compliance with 37 C.F.R. § 1.121(b)(3). In the Substitute Specification submitted herewith, every sequence is now accompanied by a “SEQ ID NO:” designation in compliance with 37 C.F.R. §§ 1.821 – 1.825. Each of these sequence identifiers (e.g., SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, etc.) was included in the Sequence Listing submitted November 17, 2006. Replacement of the originally-filed Specification with the Substitute Specification is respectfully requested.

OTHER CHANGES IN THE SUBSTITUTE SPECIFICATION

Three additional changes have been made in the Substitute Specification. First, the first paragraph of the Specification in the “Cross-Reference to Related Applications” is being replaced in order to correct a grammatical error and supply missing information. The corrected version of this paragraph was previously supplied to the Office in the Preliminary Amendment filed November 17, 2006. It should be entered into the Application, because it does not add new matter to the specification, and it serves to correct obvious defects.

Second, the Tumor Susceptibility Gene 101 protein was misnamed the “Tumor Suppressor Gene 101 protein” in Table 1 in the originally-filed Application. This

obvious defect is apparent when one refers to the GenBank record provided in Table 1 (Accession No. U82130), which describes the “Human tumor susceptibility protein (TSG101) mRNA, complete cds,” and its encoded “tumor susceptibility protein.”

Applicants respectfully submit that this change serves to corrects an obvious defect in the Application, and does not add new matter, because the correct full name of TSG101 was provided in the first sentence of Section 2.1 of the Application (see paragraph 54 of the Substitute Specification), and is also provided in the Entrez Nucleotide record associated with GenBank Accession No. U82130.

Third, several typographical errors present in the originally-filed Specification have been corrected in the Substitute Specification. This was done for the sake of clarity and completeness. Because these changes correct purely clerical errors, they introduce no new matter into the Application.

In view of the above, Applicants respectfully request entry of the Substitute Specification.

AMENDMENTS TO THE CLAIMS

In an effort to streamline and expedite examination of the Application on the merits, Applicants cancelled all originally claims (claims 1-19), and added new claims 20 through 27, in the Preliminary Amendment filed November 17, 2006. The eight new claims substantially correspond to the group of claims previously elected by the Applicants in their Response to the Restriction Requirement, issued in the Office Action mailed June 21, 2006.

As noted in the Preliminary Amendment, support for the new claims can be found throughout the specification. However, specific support for the fact that the UEV domain of the Tsg101 protein and the PTAP motif of the late domain of HIV GAGp6 are responsible for the interactions between Tsg101 and HIV GAG is found in lines 1-2, on page 25 of the specification. Additionally, support of the assertion that antibodies that bind to the UEV domain of Tsg101 can be used to interfere with or inhibit the binding of Tsg101 and HIV GAG is found in line 18, on page 12 of the specification. Further, the definition of “selectively immunoreactive” in regard to antibodies, is provided in the last

paragraph on page 17 of the specification. And finally, the fact the term “antibody,” as used in the instant specification, encompasses monoclonal antibodies, polyclonal antibodies, antibody fragments, single chain antibodies, and humanized antibodies, is found in lines 19-24 on page 17, and throughout the section of the specification entitled “3. Antibodies,” which found on pages 36 through 41.

Presently, claims 20 and 21 are being amended in order to (a) obviate the Examiner’s objections to the claims outlined on page 2 of the Office Action mailed February 26, 2007, and (b) overcome the Examiner’s rejection of claim 21 under 35 U.S.C. § 112, second paragraph, as presented on pages 2 and 3 of the same Office Action.

Entry of the amendments is respectfully requested because they place the claims in condition for allowance, or, in the alternative, in better condition for appeal, and the amendments neither necessitate additional searches on the part of the Examiner, nor add new matter to the Application.

RESPONSE TO CLAIM OBJECTIONS

Claim 20 was objected to because it used the abbreviations “Tsg101,” “HIV,” and the “UEV domain,” to describe the claimed invention. As required by the Examiner, Claim 20 has been amended in order to clearly identify the claimed subject matter, and formally define the abbreviations that are used in the dependent claims to improve readability.

It is believed that the amendments provided obviate all of the Examiners objections.

PRIORITY OF THE CLAIMED INVENTION UNDER 35 U.S.C. § 120

Applicants respectfully note that the instant Application is a continuation-in-part of, and claims priority to, PCT Application No. PCT/US02/08146, which was filed on March 14, 2002, and which, in turn, claims the benefit of U.S. Patent Application No. 09/971,549, filed on October 4, 2001. Applicants further note that support for the claimed invention, which is directed towards antibodies that immunoreact with the UEV

domain of Tsg101, can be found in U.S. Patent Application No. 09/971,549.

Specifically, U.S. Patent Application No. 09/971,549 provides:

In one embodiment, the concentration of a protein complex having Tsg101 interacting with HIV GAGp6 is reduced in cells. Various methods can be employed to reduce the concentration of the protein complex. The protein complex concentration can be reduced by interfering with the interactions between Tsg101 and HIV GAGp6. For example, compounds capable of interfering with interactions between Tsg101 and HIV GAGp6 can be administered to cells in vitro or in vivo in a patient. Such compounds can be small organic molecules capable of binding Tsg101 protein, particularly the UEV domain of Tsg101 protein, or HIV GAGp6. **They can also be antibodies immunoreactive with the Tsg101 protein or HIV GAGp6. Preferably, antibodies that bind to the UEV domain of the Tsg101 protein are used.**

U.S. Patent Application No. 09/971,549, page 3, ¶ 2, emphasis added.

Additional support for the instantly claimed invention can be found in Section 3 (pp. 45-50) and Section 5.1 (pp. 79-80) of U.S. Patent Application No. 09/971,549.

In view of this express support for the claimed invention in this properly claimed priority document, Applicants respectfully assert that, for the purposes of applying art to the claimed invention, the effective priority date for the claimed invention is well in advance of October 15, 2002 – the online publication date of Pornillos *et al.* (*Nature Struct. Biol.* 9(11):812-817 (2002); hereinafter Pornillos), which was cited in the obviousness rejections addressed below.

RESPONSE TO THE REJECTIONS

35 U.S.C. § 112, 2nd Paragraph, Indefiniteness

Claim 21 was rejected under 35 U.S.C. § 112, 2nd paragraph, as allegedly being indefinite by virtue of the use the phrase “late domain.” While Applicants note that the phrase “late domain” is a term of the art, which would be clear to the skilled artisan in the field of virology, and especially retrovirology, Applicants have followed the suggestion of the Examiner and have amended claim 21 by replacing the phrase “late domain” with “late assembly domain of HIV GAG p6.”

It is believed that the amendment provided obviates the “indefiniteness rejection” rejection under 35 U.S.C. § 112, 2nd paragraph. Consequently, Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 103(a), Obviousness

Claims 20-22 and 24-26 are rejected under 35 U.S.C. § 103(a), for allegedly being unpatentable over Pornillos in view of Mhashilkar *et al.* (*EMBO J.* 14(7):1542-1551 (1995); hereinafter Mhashilkar). Claims 23 and 27 are rejected under 35 U.S.C. § 103(a), for allegedly being unpatentable over Pornillos in view of Mhashilkar, and in further view of Rosen *et al.* (U.S. Patent Application Publication No. 2002/0048786).

Applicants respectfully assert that support for the claimed invention, as shown above, is found in U.S. Patent Application No. 09/971,549, which was filed on October 4, 2001. Consequently, the claimed invention antedates the publication of Pornillos, making both rejections under 35 U.S.C. § 103(a) moot.

In view of the facts presented above, Applicants respectfully request that the “obviousness rejections” under 35 U.S.C. § 103(a) be rescinded.

CONCLUSION

It is believed that, upon entry of the replacement specification provided herewith, the instant Application will be in full compliance with 37 C.F.R. §§ 1.821 – 1.825. It is also believed that upon entry of the amendments provided, and upon consideration of the arguments presented, all of the pending claim will be found to be in condition for allowance, and prompt notification thereof is earnestly requested. Should the Examiner determine that additional issues remain that might be resolved by a telephone conference, he is invited to contact the undersigned via his direct office line at 801-883-3463.

It is believed that no extension of time or additional fee is due with this response. If this is incorrect, an extension of time as deemed necessary is hereby requested, and the Commissioner is hereby authorized to charge any appropriate fees or deficiency, or credit any over payment, to Deposit Account no. **50-1627**.

Respectfully submitted,

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